REMARKS

Reconsideration of the application is respectfully requested. Claims 1-12, 14-17, 19, and 21-27 have been canceled without prejudice or disclaimer. Claim 13 has been amended to an independent claim format that recites 1-benzyl-4-[(5,6-dimethoxy-1-indanone)-2-yl]methylpiperidine. Claim18 has been amended to correct dependency and to clarify the claimed subject matter. No new matter has been added. Upon entry of this amendment, claims 13 and 18 will be pending and at issue.

Claim Objections

Claims 13-15 and 18 have been objected to as depending upon non-elected claims.

Claims 14-17 have been canceled, thereby rendering this objection moot as to these claims.

Claim 13 has been amended to an independent claim format reciting 1-benzyl-4-[(5,6-dimethoxy-1-indanone)-2-yl]methylpiperidine. Claim 18 has been amended to depend from claim 13. Therefore, Applicants respectfully request that this objection be withdrawn.

Enablement Rejection

Claims 13-15 and 18 have been rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. According to the Examiner, the specification enables the treatment of Aβ aggregation in the CNS, but does not enable prevention of all CNS disorders (*see* Office Action, page 2). The Examiner contends that the working examples demonstrate that donepezil decreases the amount of Aβ aggregation in cholinergic neurons, but there are no working examples that show prevention of Aβ aggregation. The Examiner concludes that undue experimentation would be required to practice the entire scope of the claimed invention which includes completely preventing all neuron disorders, including those induced by Aβ toxicity.

Claims 14-17 have been canceled, thereby rendering this rejection moot as to these claims.

Claim 13 has been amended to call for the protection of neurons from damage induced by cerebral ischemia, excitotoxicity, Aβ toxicity, or Aβ aggregation by the administerion of an effective amount of 1-benzyl-4-[(5,6-dimethoxy-1-indanone)-2-yl]methylpiperidine. Support for this amendment is found in the claims as originally filed, and throughout the specification.

Applicants submit that claim 13, as amended, is fully enabled. The examples recited in the specification (beginning on page 22 of the specification) disclose experiments wherein the claimed compound provides a protective effect to neurons from injury. Specifically, Example 1 discloses methods to protect neurons from ischemic injury; Example 2 discloses methods to protect neurons from NMDA toxicity; Example 3 discloses protection of neurons from kainic acid; Example 5 describes experiments that demonstrate protection from Aβ-induced damage; and Example 6 discloses shows the protective effect of the compounds against Aβ aggregation and Aβ-induced damage. Thus, the specification discloses actual working examples that enable the protection of CNS neurons against ischemic damage, kainic acid exposure, Aβ-induced injury, and against Aβ aggregation. In view of the working examples, undue experimentation would not be required by a person of ordinary skill in the art to carry out the claimed methods. Accordingly, the full scope of claim 13 is enabled. Applicants therefore respectfully request that this rejection be withdrawn.

Indefiniteness Rejection

Claim 13 has been rejected under 35 U.S.C. § 112, second paragraph, as indefinite. The Examiner contends that the phrase "A method of protecting neurons of the central nervous system" is unclear. According to the Examiner, "[i]t is not clear what the neurons are being protected from" (*see* Office Action, page 5). The Examiner further states that she interpreted this as meaning "prevention" of the claimed disorder.

As described above, claim 13 has been amended to more clearly recite protection of neurons from damage induced by cerebral ischemia, excitotoxicity, Aβ toxicity, or Aβ aggregation. The specification clearly describes what is meant by "methods of protecting" neurons, as well as what neurons are protected from. For instance, Example 1 discloses experiments testing the protective effect donepezil has on ischemic neurons. Protection was assessed by evaluating "whether neurons change or not," *e.g.*, by releasing excess LDH (or not). Thus, protection of neurons relates to reducing the severity of neuron damage, as measured by, for example, LDH release. Similarly, Example 5 discloses experiments wherein donepezil protected neurons from Aβ-induced damage (damage was again assessed by measuring LDH release).

In view of this disclosure, a person of ordinary skill in the art would readily understand that protection of neurons refers to maintaining neurons in a "pre-insult" state by treatment with the claimed compounds, and thus the claim language is not indefinite. *See*, e.g., *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, (Fed. Cir. 2004) ("The requirement to 'distinctly' claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles"). Therefore, the claims are not indefinite, and Applicants respectfully request that this rejection be withdrawn, accordingly.

Anticipation Rejection

Claims 13-15 and 18 have been rejected under 35 U.S.C. § 102(b) as anticipated by Emilien, et al., *Arch. Neurol.*, 57:454-459 (2000), as evidenced by Michaelis, *JPET*, 304:897-904 (2003). According to the Examiner, Emilien teaches that donepezil is an FDA-approved acetylcholinesterase [inhibitor] approved for treating Alzheimer's disease (AD). The Examiner states that treatment of neuron disorders induced by Aβ toxicity is inherently taught by Emilien, and that Michaelis teaches that Aβ plaques and Aβ toxicity are associated with AD. Thus, the Examiner concludes that donepezil would necessarily treat Aβ toxicity because it is known to treat AD (*see* Office Action, page 6).

Claims 14-17 have been canceled, thereby rendering this rejection moot as to these claims.

The pending claims are not anticipated directly or inherently by the cited prior art. In order for a reference to anticipate claims under § 102, the reference must disclose each and every limitation of the claimed invention, and must be an embodiment of the claimed invention. *Dana Corp. v. Am. Axle & Mfg., Inc.*, 61 USPQ2d 1609 (Fed. Cir. 2002). The teaching must clearly disclose the invention with a certain degree of precision, without the need for picking and choosing components. *Ex parte Westphal*, 223 USPQ 630 (Bd. Pat. App. 1983). Additionally, "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is *necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may result* from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, (Fed. Cir. 1999).

Emilien discloses that donepezil was approved by the FDA as a symptomatic therapy for mild to moderate AD (*see* Emilien, page 455, col. 2). However, Emilien does not expressly or inherently disclose the protection of neurons from damage induced by cerebral ischemia, excitotoxicity, Aβ toxicity, or Aβ aggregation as presently claimed. Therefore, Emilien does not anticipate claims 13 and 18. Applicants respectfully request withdrawal of this rejection, accordingly.

Information Disclosure Statement

Filed concurrently with this Amendment is a Supplementary Information Disclosure Statement ("IDS") and accompanying fee. Applicants respectfully request entry of the IDS into the record and consideration of the references cited therein.

CONCLUSION

In view of the above remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining that the Examiner believes can be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Dated: October 30, 2007

Respectfully submitted,

By _____

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